

BayCovin™ Instruments

Supply Chain Integration of Laboratory Instruments in industrial and GxP Environments



Bayer Business Services

Supply Chain Management and Laboratory Automation.

Product information

Current laboratory automation is typically characterized by a variety of different instruments from different vendors, a large number of different analytical methods and the usage of different information systems. To facilitate a continuous flow of information, these information systems require an online interface to the analytical instruments. BayCovin™ Instruments bridges the gap between the quality management (QM) functionality of mySAP Product Lifecycle Management (PLM) and the instrumentation at the laboratory level. BayCovin™ Instruments is lean middleware, especially designed to provide a smooth flow of information from analytical instruments to SAP® R/3. Extending the workflow to the analytical devices augments the potential of the QM functionality of mySAP™ PLM as a fully-fledged laboratory information and management system (LIMS).

Using a SAP-certified interface to QM-IDI, inspection lots created in mySAP™ PLM QM are downloaded asynchronously to the Oracle™-based BayCovin™ Instruments Server. This download does not require a permanent online connection, thereby improving system availability and performance of the laboratory IT environment.

Downloaded characteristics (final results) are enriched by characteristics specific for the analytical method. The BayCovin™ Instruments server provides the BayCovin™ Instruments client with a work list of inspections that depend on analytical method and instrumentation requirements. The client controls the laboratory devices and collects raw quality inspection data from the instruments. Additionally, the client offers manual result entry for inspection characteristics and meta data. After data acquisition the BayCovin™ database triggers automatic calculations of partial or final results. If required by quality management regulations such as GLP/GMP or FDA 21 CFR Part 11 electronic signatures can be used, for example, passwords or bio-metrics. BayCovin™ Instruments actions are monitored by a configurable audit trail. 4-eye principle for result entry and validation of results for SAP can be enforced. After validation, which is optional, the measured and calculated end results are sent back to mySAP™ PLM QM to trigger subsequent actions in the logistic chain. The data is managed and archived in compliance with FDA regulations (21 CFR Part 11) and ISO quality standards.

Remarks:

- ★ BayCovin™ is a trade mark of Bayer Business Services GmbH.
- ★ The product names SAP®, SAP® R/3, SAP® R/3 QM, mySAP™ PLM, Oracle® Server and Oracle® Client are trade marks of our suppliers. They are only used for the purpose of a COVIN product description.

Operational use & Perspectives

BayCovin™ Instruments is designed with the regulated environment in mind. Our measures for product quality are in compliance with the current GxP regulations. The increasing requirements of our customers are the major focus of our product release strategy and our support organization.

Benefit

- ★ Efficient – Manual-free result entry, automatic data acquisition, support of formula calculations, authentication and electronic signatures by biometrics, workflow control and result entry by barcode reader.
- ★ Lean – Add-on for quality management in mySAP™ PLM; small implementation projects and reduction of support costs.
- ★ Validated – BayCovin™ Instruments software life cycle is compliant with current ISO & GxP regulations and with FDA's 21 CFR Part 11 for electronic signatures, configurable authentication and configurable workflow for result validation, support of regulated and non-regulated environments.

BBS – your partner

Bayer Business Services is a service company of the Bayer AG. It offers integrated consulting and implementation products, supporting customers with innovative services for their business processes. The goal is to make a sustainable contribution to the value creation of the customers.

System requirements

SAP® R/3 (Version 4.6.B or higher)

Oracle® Server (Version 9.2.0 or higher), Oracle® Client (Version 8.0.6 or higher)

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